CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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DISCUSSION PAPER ON THE POSSIBLE REVISION OF THE INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKE (IESTI) EQUATIONS

Prepared by the eWG chaired by the Netherlands and co-chaired by Australia[1]

BACKGROUND

1. The Committee agreed at its 48th Session (April 2016) to establish an Electronic Working Group, chaired by Netherlands and co-chaired by Australia, with the following Terms of Reference[2]:

   To identify advantages and challenges that might arise from the possible revision of the current IESTI equations and the impact on risk management, risk communication, consumer protection goals, and trade. The recommendations of the international EFSA/RIVM workshop cosponsored by FAO and WHO and the discussions in CCPR48 should be taken into account.

2. The eWG joined by 33 member countries, the European Union, and 14 observer organisations. The current discussion paper was initially prepared by the Netherlands and Australia, and adapted in response to the comments received in two commenting rounds (in round 1, comments were provided by 25 countries/ organisations, in round 2, by 17 countries/organisations).

3. Any change to the IESTI equations needs careful consideration and deliberation. It is clear from the complexity of the issue, from the comments of delegations at CCPR 2016 and the variety of viewpoints expressed by the current eWG that the discussion on a possible revision of the IESTI equations will require continuous work over several years.

Introduction

4. According to the Codex Procedural Manual, the Codex Maximum Limit for Pesticide Residues (MRL or CXL) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds.[3]

5. The Manual further specifies that MRLs are based on good agricultural practice (GAP) data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable. The Manual continues by explaining that Codex MRLs, which are primarily intended to apply in international trade, are derived from estimations made by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and that JMPRs assessment should indicate that foods complying with Codex MRLs are safe for human consumption.

6. The toxicological acceptability ('safety') of the MRL is determined by estimating a life-time dietary exposure to the residue and comparing this with the Acceptable Daily Intake (ADI), and, in case the compound has acutely toxic properties, by estimating a short-term dietary exposure and comparing this with the Acute Reference Dose (ARfD)[4]. It is a matter of principle that the exposure should not exceed the ARfD or ADI when a food commodity contains residues at the level of the MRL.

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[1] See Appendix 3 for the list of participants of the eWG
[2] Rep16/PR par 193
[3] Codex Alimentarius Commission, 2016, Procedural Manual twenty-fifth edition. Section I: Basic texts and definitions.
[4] The Acute Reference Dose (ARfD) of a chemical is an estimate of the amount of a substance in food and/or drinking-water, normally expressed on a body-weight basis, which can be ingested in a period of 24 hours or less without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation. (JMPR 2002)

7. To address the estimation of the short-term intake of pesticide residues at the international level, the International Estimate of Short Term Intake (IESTI) was developed in two FAO/WHO consultations. Consistent with international developments, the National Estimate of Short Term Intake (NESTI) was defined by several member countries. Since its 1999 meeting, JMPR has performed IESTI assessments and has further refined the methodology, see Appendix 1 for the current equations.

8. In Australia and the EU, the IESTI equations are used to estimate the short term dietary intake from pesticides for both authorisation of use and MRL setting. In the EU, the IESTI equations are also used for the evaluation of enforcement results. Codex Member States which use Codex MRLs, implicitly use the IESTI equations too. Although the same IESTI equations are used, the input parameters (residues, variability factors, unit weights, large portions) may differ among international bodies (JMPR, EFSA) and individual countries. Because of differences in these input parameters, the outcome of short-term dietary risk assessments may differ for a particular commodity-pesticide combination in different parts of the world.

9. In particular, as stated by JMPR 2006, there is a concern that conducting the assessment using the HR value (highest residue from supervised trials conducted at GAP used to estimate the MRL) instead of the MRL might not assure the safety of consumers, mainly when the MRL is much higher than the HR[5] and the short-term exposure is close to 100 % of the ARfD (JMPR, 2006[6]). In addition, a number of MRLs established prior to the introduction of acute dietary risk assessment have been found to allow for residue levels that result in short term dietary exposures - as calculated with IESTI - exceeding the ARfD. This has raised concerns among the general public in some regions as to whether the MRL can be considered safe.

10. Furthermore, the use of different input parameters may create trade barriers. Therefore, an evaluation of the IESTI methodology was proposed by JMPR (2006, 2007[7], 2010[8]). In order to achieve this, JMPR recommended organising a consultation, including all relevant stakeholders. JMPR 2010 stressed the fact that to ensure international harmonisation of the methodology, changes in the IESTI equations and their input parameters cannot be implemented by JMPR alone, but should be discussed at the international level.

2015 International scientific workshop on IESTI

11. In response to the above and recognizing the need to harmonize the IESTI methodology on a world-wide level, the European Food Safety Authority (EFSA) and the Dutch WHO Collaborating Centre on Chemical Food Safety (RIVM[9]) organised a 2-day Scientific Workshop in September 2015 to seek the views of experts on the IESTI methodology. FAO and WHO co-sponsored this event, which took place in Geneva (for short: the 2015 Geneva workshop). A stakeholder meeting was held on the day before the Scientific Workshop.

12. The overall goal of the Geneva Workshop was to evaluate and where possible harmonise the parameters within the IESTI equations, as well as the equations themselves in order to propose ways to refine the methodology. To facilitate the discussions, a background document describing the issues to be discussed and proposals for possible ways forward was provided**[10]**.

    During the workshop these issues and proposals were discussed. The participants to the workshop recommended replacing the current IESTI equations (see Appendix I) by the following:

[5] When the MRL is derived with the OECD calculator, the MRL can only be much higher than the HR if it is from a small or highly variable dataset. In either case a variability estimate is included in the calculator algorithms for established MRL (mean + 4 * SD). The MRL thus incorporates the uncertainty of small or highly variable datasets. The use of a variability factor with the MRL needs further investigation.

[6] http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/JMPRrepor2006.pdf

[7] http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report07/report2007jmpr.pdf

[8] http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report10/JMPR_2010_contents.pdf

[9] RIVM is a Dutch acronym for the Dutch National Institute for Public Health and the Environment

[10] Event Report of the EFSA/RIVM Scientific Workshop, co-sponsored by FAO and WHO, 'Revisiting the International Estimate of Short-Term Intake (IESTI equations) used to estimate the acute exposure to pesticide residues via food', 8/9 September 2015, Geneva, Switzerland.
Annex A – **Background document** for the workshop
http://www.efsa.europa.eu/en/supporting/pub/907e

New IESTI equation replacing case 1 and case 3 of the current IESTI equation:

$$IESTI = LP_{bw} \times MRL \times CF \times PF$$

New IESTI equation replacing case 2a and case 2b of the current IESTI equation:
$$IESTI = LP_{bw} \times MRL \times \nu \times CF \times PF$$

13. In the proposed equations, several changes in the derivation of the input parameters were foreseen. Further background to these changes was described in the **workshop report,** in particular in the **Annex A – background document**[10]

14. A general concern that was expressed during the 2015 Geneva workshop is that the proposed equation for case 3 does not sufficiently take account of the effects of bulking and blending with respect to residue levels. This issue needs to be further addressed**.**

15. It is noted that many members of the eWG, are concerned that the equations as proposed at the 2015 Geneva workshop are unnecessarily conservative. Furthermore, it is noted that 'conservative' is a subjective term that needs to be defined for CCPR purposes.

16. Furthermore, at the Geneva workshop a list of future work was identified as required to revise the dietary risk assessment. The report of the 2015 Geneva workshop was published as an EFSA event report in December 2015. An advanced draft of the report was provided to the JMPR 2015 meeting for its consideration.

17. The JMPR 2015 discussed the draft EFSA event report and acknowledged that the short-term dietary exposure estimates derived from the two proposed IESTI equations as a whole need to be assessed. JMPR recommended that a WHO/FAO working group be established to compare the use of current and proposed equations and to present the outcome to the CCPR in due course.

18. In the eWG it was noted that if the MRL is to be incorporated into equations to estimate human pesticide intake, then it would be critical that the resulting pesticide intake estimates be evaluated against the desired level of protection, or protection goal, which then would need to be clearly established. This evaluation could be done by comparing the estimates of proposed IESTI equations with estimates generated with probabilistic based approaches that would need to be supported by JMPR or FAO/WHO. Furthermore, in connection to the above-mentioned protection goal, CCPR should consider the target percentile(s) of the exposure distribution used for regulatory decisions.

2016 CCPR

19. Two side-events[11] concerning the revision of the IESTI were organised at the 48th Session of CCPR, one by the Dutch WHO Collaborating Centre on Chemical Food Safety at RIVM with the assistance and participation of Australia, EFSA, France, Germany, and the United Kingdom, and one by CropLife. During both side-events it was acknowledged that based on preliminary assessments the implementation of all recommendations made by the 2015 Geneva workshop could lead to a loss of Codex MRLs[12]. The actual number of Codex MRLs that may be lost if the recommendations from the Geneva Workshop are implemented is unknown and simple counts of MRLs that may be lost do not necessarily appropriately reflect the trade value or other equally appropriate metrics that may be of interest. The 2015 Geneva workshop acknowledged that several aspects needed further work. If new equations are formulated and their input parameters defined, a more accurate impact assessment can be performed.

20. At its 48th Session, the Committee first discussed revisiting the IESTI under Agenda Item 5a, Report on items of general consideration by the 2015 JMPR. The Committee noted the information contained in Section 2 of the 2015 JMPR Report and the support of Codex members for such activities as follows: (Rep16/PR par 20):

[11] http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCPR&session=48

[12] A loss of Codex MRLs of up to 5% was calculated based on the JMPR residue data set 2011-2014, including only compounds where the residue definition for enforcement equals the residue definition for risk assessment (=46% of all compounds; for another 27% an ARfD was considered not necessary).The dataset contained 466 MRLs. http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-48%252FCCPR48%2Bside-event1%2Bsupport%2Bdocument.pdf

A scientific workshop co-sponsored by FAO and WHO was organised by EFSA and RIVM to discuss the methodology used to estimate the short-term dietary exposure for compounds having an ARfD. The workshop identified several elements, which could improve the scientific basis for the IESTI equations for further consideration by JMPR. The workshop also made other recommendations related to risk management and risk communication for consideration by CCPR.

21. Furthermore, under Agenda Item 11, the Committee discussed a conference room document CRD3[13] on a proposal for new work on a possible revision of the IESTI equations, prepared by EU and Australia, as follows. The Delegation of the EU highlighted the challenges the EU was facing in risk communication in relation to residue levels in enforcement samples that were compliant with the MRL but could lead to an exposure estimate exceeding the ARfD. The Delegation of the EU expressed concerns that in the long term, this might undermine public trust in the regulatory system for pesticide residues and contribute to the proliferation of private standards. The Delegation underlined the importance the EU was placing on a methodology for short-term dietary exposure assessment of pesticide residues that was harmonised at the international level, and notably within CCPR. It further recalled the considerations of JMPR in recent years on the need to revisit the IESTI equations. The Delegation clarified that the intention of their proposal was to facilitate further work to better understand the potential impact of possible changes to the IESTI equations, and encouraged other delegations to actively participate in such work[14].

22. The Delegation of Australia, co-author of CRD3, explained that the IESTI, as developed by JMPR, had been in use in their country for 15 years for the purposes of conducting dietary exposure assessments for registration and for re-evaluation of existing compounds in plant protection products. It was important for Australia and other members to make reference to best international practice for dietary exposure assessments as endorsed by FAO and WHO for harmonisation and risk communication. Science changes over time and there is an expectation that assessment methodologies should reflect best science and best practice[15].

23. The Committee's discussion indicated general support for the proposal to explore the potential impact of possible changes to the IESTI equations and highlighted the need to clearly define the issues to be addressed, how they had developed and what should be done. Delegations also acknowledged that, after being in place for more than a decade, it was time for JMPR to review the IESTI procedure and for CCPR to address the need to harmonise approaches for risk assessment, risk management and risk communication.

24. More specifically, delegations highlighted the need: to examine the impact of the parameters on the short-term dietary intake assessments derived by the current and proposed IESTI equations; to clearly define the protection goals of the proposed IESTI equations; to identify any positive or negative impact of the proposed changes in terms of number of Codex MRLs; to have a broad participation in the eWG (if established) reflecting a wide spectrum of economic development; for FAO and WHO advice on the new equation and its parameters to assist CCPR to reach a conclusion on this matter; and to evaluate the wider acceptability of the changed equation[16].

25. In view of the general support to the proposal to re-evaluate the IESTI, the Committee agreed to establish an eWG as indicated in paragraph 1~~,~~

26. The eWG identified the following list of advantages and challenges that might arise from the possible revision of the current IESTI equations. In addition, the eWG identified a list of technical challenges that, as these are not within the remit of CCPR, were gathered to be forwarded to FAO and WHO for technical/scientific consideration, see Appendix 2.

27. Please note that in the tables below, advantages and challenges are listed in random order e.g., advantage 1 has no direct relation to challenge 1.

[13] http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCPR&session=48
[14] Summarised from Rep16/PR par 184-188
[15] Adopted from Rep16/PR 189
[16] Rep16/PR par 190/191

Table 1: Advantages that might arise from the possible revision of the current IESTI equations

1	It is an opportunity to define clear protection goals and to design an equation set that is “tuned” to ensure the goals are met but without being overly conservative and without adverse trade impacts.
2	It is an opportunity to explore alternatives and revise the approach to acute dietary risk assessment by establishing a transparent, credible, and unambiguous calculation approach. There is opportunity to calibrate the revised equations using the best tools and data available for estimating likely actual short-term dietary exposure, to benchmark the level of conservatism and ensure its link to the defined protection goals.
3	Using the MRL instead of the HR in the dietary risk assessment may simplify communication of risk assessment assumptions. This will help to address concerns among the general public in some regions about the safety of MRLs.
4	Using up-to-date scientific knowledge will decrease uncertainties and improve the credibility of the methodology, e.g. on how to express the Large Portion. Additional consideration of consumption for the various types of commodities within the IESTI set of equations warrants periodic review and any new data to support such revisions should be thoughtfully considered
5	Updating the IESTI methodology, including clarification of the input parameters may increase the acceptance of CXLs.
6	Uniformity of understanding the IESTI methodology world wide
7	World-wide harmonisation of the IESTI methodology including the clarification of its parameters, may allow and facilitate its use by a larger number of countries thereby helping to prevent trade barriers.
8	HRs are based on residue data from a specific GAP. Residue data from alternative GAPs may result in a higher HR values, but if the residue value is still below the MRL, the commodity can be moved in international trade. Moving from GAP specific HRs to the MRLs in consumer risk assessment reflects in a more transparent way international trade standards irrespective of the kind of treatment.
9	The unit weight of a commodity is a poorly defined parameter. Removing it from the equation may improve the practicability and understanding of the methodology.

Table 2: Challenges that might arise from the possible revision of the current IESTI equations

1	To manage executing the technical work needed in an acceptable time frame, like developing further guidance on the derivation of conversion factors, developing databases with conversion factors and processing factors, and P97.5 large portion value derived from the distribution of consumption values of dietary surveys expressed as g/kg body weight. It is noted that part of this work would also be required to underpin the current methodology.
2	To undertake a comprehensive analysis on the impacts of any proposed changes to the IESTI methodology on existing CXLs, noting that depending on the changes agreed on, some CXLs may be lost. It is noted that the loss of CXLs may have an impact on the availability of specific pesticides and hence food production.
3	To effectively communicate/explain to the consumer, the growers, importers and exporters how some CXLs currently considered to be safe are considered unacceptable if revised IESTI equations are adopted.
4	Given the possible loss of MRLs, instructions regarding how countries can use Codex MRLs as reference for their national regulations, must be considered. It is needed to generate orientation and guidelines related to the IESTI equations in an easy-to-understand document for developing and less developed countries,.. Note that this would be useful in the current situation as well
5	To provide training regarding this equation and its potential use by the countries. Note that this would be useful in the current situation as well
6	Growers need to have pest control substances with multiple Modes of Action available to prevent the development of pesticide resistance to any single pesticide. A reduction in the number of CXLs may lead to the loss of products alternative for the grower.
7	Consideration needs to be given on how to address residues in products of animal origin e.g. the different policies in the EU compared to Codex of setting MRLs for muscle and not meat.
8	The loss of some of the current CXLs may impact global trade. This potential impact may be disproportionally affecting developing countries trading in food crops and having limited access to alternative compounds
10	Reaching consensus on the protection goal. Defining the target percentile(s) of suitable probabilistic exposure distributions that are to be estimated by the IESTI equations in order to be used for regulatory decisions.

RECOMMENDATIONS

The Committee is invited to consider the following recommendations:

28. Improving the scientific basis for the IESTI is the remit of JMPR. It is proposed that the Committee supports the recommendation by JMPR to establish a FAO/WHO technical working group that can work in between JMPR Meetings to consider the proposals that are related to risk assessment as made by the 2015 Geneva workshop (expression of LP on an individual bodyweight basis, use of CFs and PFs, loss of unit-weight for IESTI Case 2a) and to compare the use of current and proposed equations and to present the outcome to CCPR. In addition, the OECD's Residue Chemistry Expert Group might be consulted for specific questions. Furthermore, generating orientation and guidelines for developing and less developed countries would be necessary for them to interpret and use the results.

29. Risk management and risk communication are within the remit of CCPR.

30. Using the MRL instead of the HR (i.e. Highest Residue found in the relevant supervised residue trials) in the equations is a risk communication and risk management issue.

40. In addition, the Committee should agree on the consumer protection goal that should be achieved by using the IESTI. Although the level of conservativeness of the current IESTI is not clearly defined, it is well accepted world-wide. Therefore, it is proposed that changes to the IESTI should not lead to substantial changes in the level of conservativeness. The above-mentioned FAO/WHO technical working group should be requested to develop a suitable approach to quantify the differences between the current and proposed IESTI, e.g to benchmark the outcome of the current and the newly proposed IESTI to a suitable probabilistic distribution of actual exposures. To ensure that an assessment of the impact of changes to the IESTI is accepted, this approach, as developed by the FAO/WHO technical working group, should be agreed by the Committee beforehand.

41. Based on the list in paragraph 27 (Tables 1 and 2) and the findings of the FAO/WHO working group (see paragraph 28), a list of anticipated problems for trade could be established at a future session of the Committee by the eWG e.g. some MRLs or commodities could be disproportionally affected if the proposed changes are adopted. The Committee then should weigh the advantages for risk management and risk communication against the expected impact on trade.

42. It is proposed to re-establish the eWG to interact with the proposed FAO/WHO technical working group and to prepare the discussions at the Committee by further elaborating the document on advantages and challenges and anticipated impact of a possible revision of the IESTI equations on risk management, risk communication, consumer protection goals, and trade, informed by the findings of the FAO/WHO working group.

Appendix 1[17]: Acute dietary exposure estimates currently used by JMPR

LP_{person} Highest large portion reported (97.5th percentile of consumers only), kg of food per person per day.

HR Highest residue in composite sample[18] of raw edible portion found in the supervised trials performed according to GAP used for estimating the maximum residue level (in mg/kg).

HR-P Highest residue in a processed[19] commodity, mg/kg, calculated by multiplying the highest residue in the raw commodity by the processing factor.

bw Mean body weight, kg, provided by the country from which the LP was reported. The bodyweight represents the mean body weight of the population group of the dietary survey from which the LP was derived (e.g. general population, adults, children).

U_e Unit weight of the raw edible portion, kg, provided by the country where the trials that gave the highest residue were carried out.

U_{RAC} Unit weight of the raw agricultural commodity (RAC), kg, provided by the country where the trials that gave the highest residue were carried out.

v Variability factor, the factor applied to the composite residue to estimate the residue level in a high-residue unit.

STMR Supervised trials median residue in the raw edible portion of a food commodity (expressed as mg/kg), derived from the same set of supervised field trials as the HR.

STMR-P Supervised trials median residue in processed commodity (in mg/kg).

Case 1

The residue in a composite sample (raw or processed) reflects the residue level in a portion of the commodity that would be consumed at one meal (whole fruit or vegetable unit weight (expressed as RAC) is below 0.025 kg). Case 1 also applies to meat, liver, kidney, edible offal and eggs, and for grains, oilseed and pulses commodities when the estimates were based on post-harvest use of the pesticide.

$$\text{IESTI} = \frac{\text{LP}_{\text{person}} \times (\text{HR or HR - P})}{\text{bw}}$$

Case 2

The one meal portion, such as a single fruit or vegetable unit, might have a higher residue than the composite (whole fruit or vegetable unit weight (expressed as RAC) is equal or above 0.025 kg).

Case 2a

The unit weight (raw edible portion) of the commodity is lower than the large portion weight.

$$\text{IESTI} = \frac{\{\text{U}_\text{e} \times (\text{HR or HR - P}) \times \nu\} + \{(\text{LP}_{\text{person}} - \text{U}_\text{e}) \times (\text{HR or HR - P})\}}{\text{bw}}$$

The case 2a formula is based on the assumption that the first unit contains residues at the [HR × *v*] level and the next ones contain residues at the HR level, which represents the residue in the composite from the same lot as the first one.

Case 2b

The unit weight (raw edible portion) of the commodity exceeds the large portion weight.

$$\text{IESTI} = \frac{\text{LP}_{\text{person}} \times (\text{HR or HR - P}) \times \nu}{\text{bw}}$$

The case 2b formula is based on the assumption that there is only one consumed unit and it contains residues at the [HR × *v*] level.

[17] From Annex A – **Background document** in the Event Report of the EFSA/RIVM Scientific Workshop, co-sponsored by FAO and WHO, 'Revisiting the International Estimate of Short-Term Intake (IESTI equations) used to estimate the acute exposure to pesticide residues via food', 8/9 September 2015, Geneva, Switzerland.
http://www.efsa.europa.eu/en/supporting/pub/907e

[18] Composite sample = samples composed of multiple units of the same commodity

[19] 'Processing' can either relate to removing inedible parts of a commodity, e.g. peeling a banana, or to further (industrial or household) preparation, e.g. milling of grain, cooking of spinach.

Case 3

Case 3 is for those processed commodities where, because of bulking or blending, the STMR-P represents the likely highest residue. Case 3 also applies to milk and to grains, oilseeds and pulses for which the estimates were based on pre-harvest use of the pesticide.

$$\text{IESTI} = \frac{\text{LP}_{\text{person}} \times (\text{STMR or STMR - P})}{\text{bw}}$$

The concept of variability factor was introduced to take into account the different concentrations of residues in individual portions of a composite sample and average residue concentration in the sample lot represented by the composite sample. The variability factor (*v*) was defined as the 97.5th percentile of the residue concentrations present in commodity units (RAC) divided by the mean residue concentration of the sample population: P97.5 residue in units / mean residue in units.

In the IESTI methodology, the estimates are performed for each crop individually, as it is unlikely that an individual will consume, within a meal or 24 h, a large portion of more than one food containing the highest residue level (the one that incorporates the variability factor). The IESTI calculations can be performed separately to estimate dietary exposure from consumption of the unprocessed or processed form of a food commodity, when relevant.

Appendix 2, Table 3: Technical / risk assessment challenges that either arise from the possible revision of the current IESTI equations, or are current challenges as well. To be forwarded to the FAO/WHO working group

1	Developing further guidance on the derivation of conversion factors, and developing a database with conversion factors
2	Developing a database with processing factors,
3	A database with P97.5 large portion value derived from the distribution of consumption values of dietary surveys expressed as g/kg body weight is needed. Internationally agreed criteria must be developed for dietary surveys, used for the assessment of consumer exposure. It is noted that this is ongoing work by WHO/ GEMS Food.
4	Information on bulking and blending practices needs to be gathered in order to decide on cases where a median residue instead of the MRL could be used in the dietary risk assessment, or a homogenization factor could be added (see item 13).
5	Clarify the influence of the number of supervised field trials used for the OECD MRL Calculator, where small data sets result in high MRL estimates. It is noted that this especially affects minor crops with low data requirements.
6	The suitability of common moiety residue definitions needs to be reconsidered when multiple active substances are included (e.g. CS_2 for all dithiocarbamates) and one of those is potentially exceeding the ARfD.
7	The acute exposure assessment using the proposed IESTI will merely depend on the LP_{bw} values. Especially LP of children are crucial in risk assessment. The food consumption data are very heterogeneous and based on dietary survey studies of different design, quality and origin. An important reason for heterogeneity is also the preference of certain foods by the population. The more popular a particular food, the more data are available and the more reliable and robust are the P97.5 values. A pragmatic approach has to be established which addresses this issues; e.g. setting the same consumption value for a group of commodities (extrapolation rules).
8	Further guidance/decision making needed on the use of the variability factors relative to the MRL. The current use of the variability factor is not considered to be mathematically appropriate for use with an MRL by many members of the eWG. Using the MRL with current variability factors is considered to be overly conservative and leading to loss of MRLs and disruption of global trade. Since MRLs are now determined consistently by algorithms in the OECD MRL calculator simulation modeling to determine how single item residues might relate to the MRL could be useful. Others consider that the variability factor describes the inhomogeneity of residues on individual units from an unknown lot in relation to a composite sample collected according to Codex sampling procedures. The Codex sampling procedure is also the basis for MRL compliance testing – therefore the relative inhomogeneity (variability) in lots at or above the MRL is identical to lots with lower residues measured in a composite sample. The variability factor to be used remains unaffected. Also, the OECD MRL procedure only considered results from composite field trial samples and includes no extrapolation to individual units as it is described by the new IESTI case 2.
9	To quantify uncertainties related to the use of the IESTI equations as far as possible, and to qualitatively describe the uncertainties that cannot be quantified.
10	To estimate the impact of removing the unit weight from the equation and especially for case 1 and case 2 which distinction currently relies on the unit weight.
11	Reaching consensus regarding the approach to be used to evaluate the level of conservatism of proposed updated IESTI equations and how it compares to both the present set of IESTI equations and state-of-the-science probabilistic methods.

12	Current consumption data on processed commodities in some territories of the world are not available. Many crops which are consumed in large amounts in the processed form (e.g. apples or citrus consumed as juice) will be disproportionately considered when estimating the acute exposure on the basis of consumption data of non-processed commodities only, hampering a meaningful estimate of the acute exposure. Therefore consumption data of processed commodities and recipe data need to be collected from a representative range of countries..
13	For blended foods (e.g. fruit juice, seed/nut oil, flour, corn meal), it is suggested to add a homogenization factor (<1) to the equation to reflect the decreased variability in pesticide residues resulting from processing.
14	The comparison of the deterministic IESTI with probabilistic models is challenging. First the database itself needs to be identical. Second, the results will differ commodity by commodity – how are general conclusions drawn for the equation itself? Third, the probabilistic methodology requires careful preparation and agreement. Especially for the consumption data the aggregation of commodities should be the same for both approaches (e.g. LP for apples, raw vs. apples raw in probabilistic; not LP for total apples expressed as raw vs. all individual foods containing apple).

Appendix 3:
List of Participants of the eWG

Chair: Dr. Bernadette Ossendorp
Head Dept. Food Safety RIVM
(Dutch National Institute for Public Health and Environment)
PO Box 1 Bilthoven Netherlands
Email: bernadette.ossendorp@rivm.nl

Co-Chair: Mr. Ian Reichstein
Director National Residue Survey, Residues & Food, Exports Division
Australian Government, Department of Agriculture and Water Resources
Email: Ian.reichstein@agriculture.gov.au

ARGENTINA
Ms Laura Bonomi
SENASA Servicio Nacional de Sanidad y Calidad Agroalimentaria lbonomi@senasa.gov.ar

Argentinian codex contact point
Dirección de Cooperación y Negociaciones Bilaterales, Dirección Nacional de Relaciones Agroalimentarias Internacionales, Ministerio de Agroindustria
codex@magyp.gob.ar

AUSTRALIA

Dr Dugald Maclachlan
Director Residues and Food SafetyAustralian Government, Department of Agriculture and Water Resources
Dugald.maclachlan@agriculture.gov.au

Dr Jason Lutze
A/g Executive Director, Scientific Assessment and Chemical Review
Australian Pesticides and Veterinary Medicines Authority (APVMA)
Jason.lutze@apvma.gov.au

Australian codex contact point Department of Agriculture and Water Resources codex.
contact@agriculture.gov.au

BELGIUM
Mr Wim Hooghe
wim.hooghe@health.belgium.be

Contact point of the Belgian Committee for the Codex Alimentarius codex.be@health.belgium.be

BRAZIL
Mr Carlos Ramos Venancio
Head of Pesticide Registration Division Ministry of Agriculture Livestock and Food Supply
carlos.venancio@agricultura.gov.br

Mr Rogério Pereira da Silva
Coordinator for Codex Alimentarius MattersMinistry of Agriculture Livestock and Food Supply
rogerio.silva@agricultura.gov.br

CANADA
Ms Jennifer Selwyn
Section Head, Minor Use Assessment SectionHealth Canada; Health Evaluation Directorate, Pest Management Regulatory Agency
Jennifer Selwyn@Canada.ca

Ms.Isabelle Pilote
Section Head, Exposure 2 Fungicides/HerbicidesHealth Canada;
Health Evaluation Directorate, Pest Management Regulatory Agency
Isabelle.Pilote@Canada.ca

Dr.Peter Chan
Director General, Health Evaluation Directorate
Health Canada; Pest Management Regulatory Agency
Peter.Chan@HC-SC.gc.ca

CHILE
Roxana Inés Vera Muñoz
Coordinator for the International Affaits Division Unit at the Livestock and Agriculture Service, SAG. Coordinator for the National CCPR
Livestock and Agriculture Service (SAG)
ccpr.chile@sag.gob.cl

Paulina Chávez
Technical advisor, Department of Foods and Nutrition, Ministry of Health, Deputy-Coordinator for the National CCPR Subcommittee.
Ministry of Health, Department of Foods and Nutrition
pchavez@minsal.cl

Diego Varela
Chilean Codex Contact Point
Food Safety and Food Quality Agency (ACHIPIA)
codex@achipia.gob.cl

COSTA RICA
Verónica PICADO POMAR
Jefe de Laboratorio
Servicio Fitosanitario del Estado, MAG; Laboratorio de Análisis de Residuos de Plaguicidas
vpicado@sfe.go.cr

Amanda LASSO CRUZ
Licensed Food Technologist
Ministry of Economy, Trade and Industry; Department of Codex
alasso@meic.go.cr

Ms Nguyen Thi Bich Lieu
Management Assistant CropLife International aisbl, Brussels
Lieu.nguyen@croplife.org

DENMARK
Bodil Hamborg Jensen
Senior adviser
DTU, National Food Institute, Division for Risk Assessment and Nutritionbhje@food.dtu.dk

EUROPEAN UNION
Almut Bitterhof
Head of Unit
European Commission Almut.bitterhof@ec.europa.eu

Volker Wachtler
Administrator
European Commission
volker.wachtler@ec.europa.eu

Christophe Didion
Administrator
European Commission
Christophe.DIDION@ec.europa.eu

Veerle van Heusden
Administrator
European Commission
Veerle.VANHEUSDEN@ec.europa.eu

Hermine Reich
European Food Safety Authority
Hermine.REICH@efsa.europa.eu

FINLAND
Ms Tiia Mäkinen-Töykkä
Senior Inspector
Finnish Food Safety Authority
Eviratiia.makinen@evira.fi

FRANCE
Ms Florence GERAULT
National expert on pesticide residues and other contaminants
Ministère de l'Agriculture, de l'Agro-alimentaire et de la Foretflorence.
gerault@agriculture.gouv.fr

Ms Gaelle VIAL
Scientific assessor
Unité Résidus et Sécurité des Aliments, ANSES
gaelle.vial@anses.fr

Mr Nicolas BREYSSE
Scientific assessor
Unité Résidus et Sécurité des Aliments, ANSES
nicolas.breysse@anses.fr

Dr Xavier SARDA
Head of unit
Unité Résidus et Sécurité des Aliments, ANSES
xavier.sarda@anses.fr

GERMANY
Dr Angela Göbel
Federal Ministry of Food and Agriculture
313@bmel.bund.de

Mr Christian Sieke
Federal Institute for Risk Assessment - Residues and Analytical Methods christian.sieke@bfr.bund.de

INDIA
Dr P.K. Chakrabarty
Assistant Director General (Plant Protection & Biosafety)
Indian Council of Agricultural Research
adgpp.icar@nic.in; pranijbc@hotmail.com

Dr K.K. Sharma
Network Coordinator
Indian Council of Agricultural Research
kksaicrp@yahoo.co.in

Codex Contact Point of India
codex-
india@nic.in

INDONESIA
Ms Feni Amriani
Researcher
Indonesian Institute of Science
feni.amriani@lipi.go.id; feni.chem1@gmail.com;
bidang_kps@yahoo.co.id

IRAN, ISLAMIC REPUBLIC OF
Dr Mohammad Kazem Ramezani
Research Scientist
Pesticides Research Department
Iranian Research Institute of Plant Protection (IRIPP), Environment & Food Safety Office
Institute of Plant Protection (IRIPP), Environment & Food Safety Office

Roya Noorbakhsh
Expert on Pesticide residue in food & Secretary of national codex committee on CCPR in Iran
Standard Research Institute, Faculty of Food & Agriculture
roybakhsh@yahoo.com

ITALY
Dr Angela Santilio
Researcher
Environmental and Primary prevention Department, Italian National Institute of Health
angela.santilio@iss.it

JAPAN
Dr Yukiko YAMADA
Guest Scholar
National Institute of Health Sciencescodexj@mhlw.go.jp

Mr Yoshiyuki MATSUBARA
Special Assistant
Standards and Evaluation Division, Department of Environmental Health and Food Safety, Ministry of Health, Labour and Welfare
codexj@mhlw.go.jp

Mr Nobuyuki Hamasuna
Deputy Director
First Risk Assessment Division, Food Safety Commission Secretariat, Cabinet Office
fscj-pesticide@cao.go.jp;
nobuyuki.hamasuna.r5w@cao.go.jp

Mr Makoto IRIE
Deputy Director
Plant Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agiculture, Forestry and Fisheries
makoto_irie340@maff.go.jp; codex_maff@maff.go.jp

KENYA
Ms Lucy M. Namu
Head Quality Assurance and Laboratory Accreditation
Kenya plant Health Inspectorate Service(KEPHIS)
lnamu@kephis.org

KOREA, REPUBLIC OF
Codex Korea Contact Point
Ministry of Food and Drug Safety (MFDS)
codexkorea@korea.kr

Codex contact point of Republic of Korea Ministry of Agriculture, Food and Rural Affairs (MAFRA)
codex1@korea.kr

Dr Chang Moon-Ik
Deputy Director, Pesticide & Veterinary Drug Residue Division
Ministry of Food and Drug Safety (MFDS)
1004@korea.kr

Dr Chan-Hyeok Kwon
Scientific Officer, Livestock Product Standard Division
Ministry of Food and Drug Safety (MFDS)
chkwon@korea.kr

Dr Hyo-Chin Kim
Scientific Officer, Livestock Product Standard Division
Ministry of Food and Drug Safety (MFDS)
hckim77@korea.kr
Kyeong-ae Son
National Institute of Agricultural Sciences
sky199@korea.kr

MALAYSIA
En Mohamad Nazrul Fahmi Abdul Rahim
nazrulfahmi@doa.gov.my

En Hayusri Faizal Idris
hayusri@doa.gov.my

Codex Contact Point Malaysia
ccp_malaysia@moh.gov.my

MALTA
Ms Nicole Cilia
Professional Scientific Officer
Regulatory Affairs Directorate, Technical Regulations Division, Malta Competition & Consumer Affairs Authority
nicole.cilia@mccaa.org.mt

MAROCCO
Mr Ahmed JAAFARI
Chef Service des Intrants Chimiques
ahmedjaafari@yahoo.fr

Mr Ahmed ZOUAOUI
Chef Service Pesticides LOARC
zouaouiloarc@yahoo.fr

Dr Beqqali Himdi Ihssane
Contact point Codex MAROC
Office National de Sécurité Sanitaire des produits Alimentaires
cnc.ma@ONSSA.GOV.MA

NETHERLANDS
Dr Martijn Martena
Policy Officer Department of Nutrition, Health Protection and Prevention
Ministry of Health, Welfare and Sport
mj.martena@minvws.nl

Dr Anton Rietveld
Senior adviser
Dutch National Institute for Public Health and the Environment (RIVM) anton.rietveld@rivm.nl

Mr Arie Ton
Scientific Assessor Consumer Safety
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
Arie.Ton@ctgb.nl

Mr Henk van der Schee
Wetenschappelijk medewerker
Nederlandse Voedsel- en Warenautoriteit
h.a.vanderschee@nvwa.nl

Dr Marie-Ange Delen
National Codex coordinator
Ministry of Economic Affairs
info@codexalimentarius.nl

NEW-ZEALAND
Warren Hughes
Principal Adviser
Ministry for Primary Industries
warren.hughes@mpi.govt.nz

NIGERIA
Oluyemisifoluso Odofin
Chief Regulatory Officer
National Agency for Food and Drug Administration and Control (NAFDAC)
odofinoluyemisi@yahoo.com

Nigerian Codex Contact Point
codexsecretariat@son.gov.ng; megesciett@yahoo.com

NORWAY
Hanne Marit Gran
Senior Adviser
Norwegian Food Safety Authority
Hanne.Marit.Gran@mattilsynet.no

Codex Contact Point Norway
codex@mattilsynet.no

PERU
Ing Humberto REYES CERVANTES
Coordinator holder
SENASA (National Service of Agrarian Health)
ereyesc@senasa.gob.pe

Ing Susan DIOSES CORDOVA
Alternate coordinator
SENASA (National Service of Agrarian Health)
sdioses@senasa.gob.pe

POLAND
Dr Paweł Strucinski
Senior Researcher, Head of Environmental Contaminants and Risk Assessment Unit National Institute of Public Health
National Institute of Hygiene; Department of Toxicology and Risk Assessment
pstrucinski@pzh.gov.pl

Polish Codex Contact Point
kodeks@ijhars.gov.pl

SPAIN
Mr César Casado de Santiago
Head of pesticide residues Service
Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN); Ministry of Health, Social Services and Equality
fitosani@msssi.es

SWITZERLAND
Mr Emanuel Hänggi
Scientific Officer
Federal Food Safety and Veterinary Office FSVO
Emanuel.Haenggi@blv.admin.ch

THAILAND
Mr Pisan Pongsapitch
Deputy Secretary General
National Bureau of Agricultural Commodity and Food Standards
pisan@acfs.go.th

Ms Panpilad Saikaew
Standards Officer
Office of Standard Development, National Bureau of Agricultural Commodity and Food Standards
panpilad@acfs.go.th;
pls_pilad@gmail.com

Ms Dawisa Paiboonsiri
Standards Officer
Office of Standard Development, National Bureau of Agricultural Commodity and Food Standards
dawisa.p@gmail.com

Codex Contact Point of Thailand
National Bureau of Agricultural Commodity and Food Standards.
codex@acfs.go.th;

UGANDA
Mr Geoffrey ONEN
Principal Government Analyst; head delegate at CCPR
Government Chemist and Analytical Laboratory
onengff@hotmail.com

UNITED KINGDOM
Dr Julian Cudmore
Chemistry and Residues Specialist
Health & Safety Executive
julian.cudmore@hse.gsi.gov.uk

UNITED STATES OF AMERICA
Dr David Miller
Branch Chief
U.S. Environmental Protection Agency, Office of Pesticide Programs
miller.davidj@epa.gov

Ms Maria Maratos
International Issues Analyst
US Department of Agriculture, Food Safety and Inspection Service, US Codex Office
Marie.Maratos@fsis.usda.gov

AGROCARE LATINOAMERICA (FORMERLY CALLED ALINA)
Lic. Amanda Francisco
AgroCare Latinoamerica (formerly called ALINA; Latinamerican Association of the National Agrochemical Industries)
amanda@aenda.org.br

Lic. Laura B. Ruiz
AgroCare Latinoamerica (formerly called ALINA; Latinamerican Association of the National Agrochemical Industries)
lruiz@alinainternacional.org

CROPLIFE INTERNATIONAL
Dr Cheryl Cleveland
Global Consumer Safety
BASF Corporation
cheryl.cleveland@basf.com

GAFTA
June Arnold
Head of Policy International Grain and Feed Trade Organisation
Junearnold@gafta.com

GPC
Gord Kurbis
Chairman of the Codex Working Group Global Pulse Confederation
gkurbis@pulsecanada.com

Lois Rossi
Consultant
Global Pulse Confederation
rluisa1@aol.com

Karen Hulebak
Consultant
Global Pulse Confederation
Karen.Hulebak@gmail.com

Morgane Danielou
Global Pulse Confederation (GPC) SecretariatGlobal Pulse Confederation
Morgane@emergingag.com

Ben Robinson
Global Pulse Confederation (GPC)
Secretariat Global Pulse Confederation
Ben@emergingag.com

Hapsa Dia
Global Pulse Confederation (GPC)
Secretariat Global Pulse Confederation
Hapsa@emergingag.com

Todd F Scholz
Vice President for Research, USA Dry Pea & Lentil Council
Global Pulse Confederation
tscholz@usapulses.org

ICA
Laura Shumow
Vice President, Scientific and Regulatory Affairs
National Confectioners Association
Laura.Shumow@CandyUSA.com

ICBA
Dr Ronald Williams, Jr.
Advisor to ICBA International Council of Beverages Associations
ronaldwilliams@coca-cola.com

ICGMA
Dr Manojit Basu
Technical Lead, Science and Regulatory Affairs
International Council of Grocery Manufacturers Associations
mbasu@gmaonline.org

IFFA
Dr
Sanjay Gummalla
Vice President, Regulatory and Technical Affairs
International Frozen Food Association
sgummalla@affi.com

IFU
Dr David Hammond
Fruit Juice Expert
International Fruit and Vegetable Juice Association
Davidfruitjuice@aol.com

IICA
Dr Horrys Friaca
Agricultural Health and Food Safety Specialist Inter-American Institute for Cooperation on Agriculture (IICA)
Office in the United States
horrys.friaca@iica.int

INC
Dr. Gabriele Ludwig
Official representative to participate in the eWG on revisiting the IESTI
International Nut and Dried Fruit Council
gludwig@almondboard.com

Ms Irene Gironès
Scientific and Technical Projects Manager
International Nut and Dried Fruit Council
irene.girones@nutfruit.org

IOSTA
Cheryl Deem
Secretariat
International Organization of Spice Trade Associations
cdeem@astaspice.org

ISC
James R. Cranney, Jr.
International Society of Citriculture (ISC)
jcranney@calcitrusquality.org

IUPAC
Dr Caroline Harris
IUPAC
charris@exponent.com